DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–1218]

Blood Standards; Pilot Program for Licensing Gamma Irradiated Blood and Blood Components and "Guidance for Industry: Gamma Irradiation of Blood and Blood Components;" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Guidance for Industry: Gamma Irradiation of Blood and Blood Components: A Pilot Program For Licensing,'' dated February 2000. FDA is also announcing the establishment of a pilot program for licensed blood product manufacturers seeking to market irradiated blood components in interstate commerce. The pilot program is intended to allow self-certification in lieu of the submission of a detailed biologics licence application (BLA) supplement. FDA is initiating the pilot program to determine if streamlining the process of licensing will be more efficient and effective for both the manufacturer and FDA without compromising product safety, purity, and potency.

DATES: Written comments may be submitted at any time. The effective date for implementation of the pilot program is [*insert date 30 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written requests for single copies of the guidance entitled ''Guidance for Industry: Gamma Irradiation of Blood and Blood Components: A Pilot Program for Licensing,'' to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office

in processing your requests. The guidance document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit requests for participation in the pilot program to Mary Ann Denham at the address below.

FOR FURTHER INFORMATION CONTACT:

About participation in the pilot program:

Mary Ann Denham, Center for Biologics Evaluation and Research (HFM–375), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–2861.

About this notice:

Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance document entitled ''Guidance for Industry: Gamma Irradiation of Blood and Blood Components: A Pilot Program For Licensing,'' dated February 2000. This guidance document is intended to assist manufacturers of gamma irradiated blood and blood components to self-certify conformance to specific criteria as part of a pilot program in lieu of the submission of a detailed BLA supplement filing. Instead of submitting a BLA supplement with supporting operating procedures and data derived from validation and quality control testing, the manufacturer may submit an application form (Form FDA 356h), a self-

certification statement that provides that the manufacturer is in compliance with all applicable FDA regulations and meets the criteria for gamma irradiated blood and blood components set forth in the guidance document entitled ''Guidance for Industry: Gamma Irradiation of Blood and Blood Components: A Pilot Program For Licensing,'' dated February 2000, as well as written request to the CBER Director for an exception to filing a detailed supplement. The pilot program provides that FDA will review for completeness Form FDA 356h, the self-certification, and written request for an exception to filing a detailed supplement, and at FDA discretion, will schedule a prelicense inspection within 90 days of receipt of the self-certification to confirm conformance with applicable Federal regulations and the recommended criteria contained in the guidance document.

This guidance document finalizes the draft guidance entitled ''Guidance for Industry: Gamma Irradiation of Blood and Blood Components: A Pilot Program For Licensing'' that was announced in the **Federal Register** of January 27, 1999 (64 FR 4118).

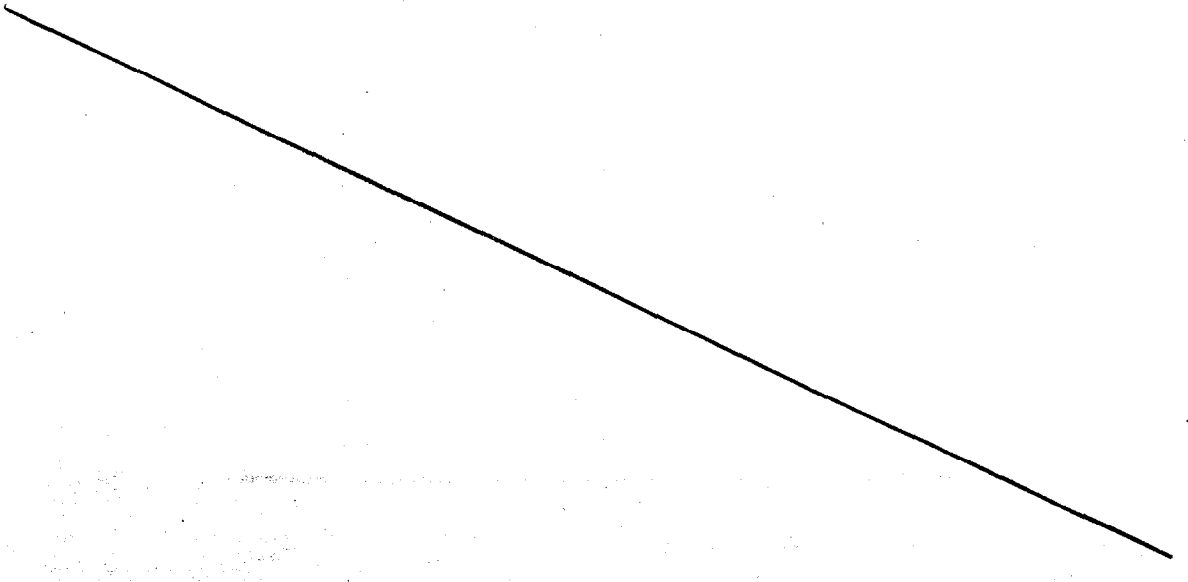
To participate in the program a manufacturer should already be licensed for nonirradiated blood components and should be ready for a prelicense inspection at the time it forwards Form FDA 356h, self-certification, and request for exception to FDA. If, during the prelicense inspection, FDA finds significant deficiencies in quality assurance, manufacturing facilities, or product safety, purity, potency, or effectiveness, FDA may withdraw the manufacturer from the pilot program, and the manufacturer will be required to submit a BLA supplement with complete supporting documentation prior to marketing irradiated blood components in interstate commerce.

FDA intends the pilot program to span approximately 1 year, but the actual length of the program depends on the number of manufacturers participating in the program. FDA will begin the pilot program on [*insert date 30 days after date of publication in the* **Federal Register**]. At the end of the pilot program, FDA will evaluate the program for efficiency and effectiveness and will make this evaluation available to the public. If the program proves to be efficient and effective, FDA will consider extending the program to other blood products.

This guidance document represents the agency's current thinking on gamma irradiation of blood and blood components intended for transfusion or for further manufacturing. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. If a manufacturer chooses to participate in this voluntary program, it should conform to the specific criteria set forth in this guidance. Manufacturers who want to use an alternative approach must submit a detailed BLA supplement under 21 CFR 601.12 or otherwise satisfy FDA that an exemption from that requirement is justified under 21 CFR 640.120. As with other guidance documents, FDA does not intend this guidance document to be all-inclusive and cautions that not all information may be applicable to all situations.

II. Comments

Interested persons, may at any time, submit written comments to the Dockets Management Branch (address above) regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this guidance document. A copy of the guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.



III. Electronic Access

Persons with access to the Internet may obtain the guidance document using the Internet. For Internet access, connect to CBER at http://www.fda.gov/cber/guidelines.htm.

Dated: 3/1/00
March 1, 2000

Margaret M. Dotzel
Acting Associate Commissioner for Policy

[FR Doc. 00–???? Filed ??–??–00; 8:45 am]

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